

REMARKS

The Office Action dated February 9, 2004, has been received and reviewed.

Claims 21-33, 45, and 46 remain pending and under consideration in the above-referenced application. Each of claims 21-33, 45, and 46 stands rejected.

Reconsideration of the above-referenced application is respectfully requested.

Rejections Under 35 U.S.C. § 112, Second Paragraph

Claims 21-33, 45, and 46 stand rejected under the second paragraph of 35 U.S.C. § 112 for purportedly being indefinite. Specifically, the Office asserts that the following recitations in claim 21 are indefinite: “which indicate binding . . .” and “. . . binding of the at least one indicator of coronary artery disease by a capture molecule . . .” The rejections of all of the remaining claims are apparently based upon their dependencies from independent claim 21.

The recitation “. . . fluorescently labeled tracer molecules, which indicate binding . . .” has been replaced with the clearer equivalent “. . . fluorescently labeled tracer molecules that indicate binding . . .”

In addition, the recitation “. . . binding of the at least one indicator of coronary artery disease *by* a capture molecule . . .” (emphasis supplied) has been replaced with the broader “. . . binding of the at least one indicator of coronary artery disease *with* a capture molecule . . .” (emphasis supplied), as was recommended by the Office.

In view of these revisions, which do not narrow the scope of independent claim 21 and, thus, should not be considered to narrow the scope of equivalents that are available in determining the scope of independent claim 21, it is respectfully submitted that independent claim 21 complies with the definiteness requirement of 35 U.S.C. § 112, second paragraph. Accordingly, withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of independent claim 21 is respectfully requested, as is withdrawal of the 35 U.S.C. § 112, second paragraph, rejections of claims 22-33, 45, and 46, each of which depends either directly or indirectly from independent claim 21.

Rejections Under 35 U.S.C. § 103(a)

Claims 21-33, 45, and 46 stand rejected under 35 U.S.C. § 103(a).

The standard for establishing and maintaining a rejection under 35 U.S.C. § 103(a) is set forth in M.P.E.P. § 706.02(j), which provides:

To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

Foster in View of Jackowski

Claims 21-33 and 46 stand rejected under 35 U.S.C. § 103(a) for reciting subject matter which is allegedly unpatentable over the subject matter taught in U.S. Patent 5,485,277 to Foster (hereinafter "Foster"), in view of teachings from U.S. Patent 5,747,274 to Jackowski (hereinafter "Jackowski").

Foster teaches a surface plasmon resonance ("SPR") system, which, as is well known in the art, includes a waveguide with a thin layer of metal on at least one surface thereof. *See, e.g.*, Foster, col. 1, lines 14-58; col. 5, lines 10-27; Jackowski, col. 28, lines 21-25. Light that is incident upon the thin metal film couples into surface nodes, which are associated with oscillations of electrons in the thin metal film. *See, id.* Additionally, as the Office has pointed out, an evanescent field is generated over the thin metal film. Foster, col. 11, lines 63-67; col. 14, lines 57-60. If capture molecules on the thin metal layer have bound analyte, the angular position of SPR changes. *See*, Foster, col. 5, lines 10-27.

Measurements of the change in the change of SPR, which are obtained from a detector positioned to face an edge of the waveguide, are used to measure the presence or absence of the analyte, as well as levels of the analyte that are present in a sample. *See*, col. 8, lines 21-24; FIGS. 4(b), 5(b), 6(b). As stated in Foster "the SPR resonance position [is] measured," wherein

"[t]he dark bands, 250, shown toward the right side of FIGS. 8(a) and 8(b) correspond to those rays that couple to the surface plasmon resonance and are thus attenuated. The focused beam, 251, is refracted, 252, when it enters the waveguide, 60. The position of the attenuated band is monitored by a CCD array. As the surface plasmon resonance position shifts, the dark band sweeps across the CCD array in proportion to the concentration of target analyte that binds to the recognition layer." Foster, col. 10, lines 62-63; col. 10, line 65, to col. 11, line 6.

Among a wide variety of assay techniques, including SPR-type waveguides, Jackowski describes that fluorescently labeled antibodies, used in either competition or sandwich-type assays, may be used in optical waveguide-type assay systems. Col. 28, lines 12-21. The description of Jackowski is, however, limited to the use of such devices in a way that fluorescent signals are "discriminated by [their] angular divergence upon exiting the waveguide." Col. 28, lines 20-21.

It is well known by those of ordinary skill in the art of optical waveguides that when fluorescent light exits a waveguide, it exits through an end or edge of the waveguide, and the angle of divergence of the exiting radiation is measured at or adjacent to that end or edge to provide some indication of the reaction that has occurred at the surface of the waveguide. This knowledge is evidence by U.S. Patent 5,166,515 to Attridge (hereinafter "Attridge"), a copy of which is enclosed for the sake of convenience. FIG. 2(a) of Attridge and the accompanying text at col. 6, lines 13-28, indicate that fluorescent light that is emitted from fluorophores at or near a major surface of the waveguide 23 may enter the waveguide (see reference character 35) and be internally reflected within the waveguide 23. The fluorescent light 35 eventually exits the waveguide 23 through an edge 25 thereof, at which edge 25 the exit angle is determined. *See id.* Again, the measurement of the angular divergence of fluorescent light as it exits a waveguide is only the type of detection described in Jackowski.

Independent claim 21, as proposed to be amended herein, is directed to an assay system for analyzing a biological liquid sample comprising, among other things, a waveguide, a light source, and a light detector. The waveguide is configured to generate an evanescent field over at least one planar surface thereof as light is directed therein. The waveguide also includes capture molecules for at least one indicator of coronary artery disease on the at least one planar surface

thereof. Fluorescent light is emitted as fluorescently labeled tracer molecules that indicate binding of the at least one indicator of coronary artery disease by a capture molecule are excited by the evanescent field. The light detector may detect the fluorescent light that passes through the major surfaces (*i.e.*, the at least one surface and an opposite surface) of the waveguide.

It is respectfully submitted that a *prima facie* case of obviousness has not been set forth against amended independent claim 21 for several reasons.

First, it is respectfully submitted that neither Foster nor Jackowski teaches or suggests each and every element of amended independent claim 21. Specifically, Foster and Jackowski both lack any teaching or suggestion of an assay system that includes a light detector for detecting fluorescent light that passes through the major surfaces of the waveguide.

More specifically, Foster lacks any teaching or suggestion of fluorescently labeled tracer molecules, as are required by the assay system recited in independent claim 21. Even, assuming, for the sake of argument, that Foster did teach that fluorescently labeled molecules could be used with the SPR-type waveguide thereof, the thin metal layer on the surface of that SPR-type waveguide would prevent any fluorescence emitted by such molecules from passing through the metal-coated surface of the waveguide and, thus, from being sensed by a detector, as recited in amended independent claim 21.

Moreover, Jackowksi neither teaches nor suggests that fluorescent light that passes through the major surfaces of the waveguide mentioned therein may be detected. Instead, as noted previously herein, the teachings of Jackowski are limited to discriminating the angular divergence of fluorescent signals as they exit the waveguide through an edge thereof. Col. 28, lines 20-21; *see also*, Attridge, FIG. 2(a); col. 6, lines 13-28.

Second, it is respectfully submitted one of ordinary skill in the art would have no reason to expect that a combination of the teachings of Foster and Jackowski, when considered in their entireties, as required by M.P.E.P. § 2143.03, would be successful. In particular, because the SPR-type waveguide of Foster includes a thin metal film on the surface thereof where a reaction between capture molecules and analyte is to take place, one of ordinary skill in the art would have no reason to expect that any fluorescence emitted as a result of such reactions would pass

through the waveguide for detection – the fluorescence could not pass through the thin metal film or, therefore, through the major surfaces of the waveguide.

Third, in view of elements of amended independent claim 21 that are neither taught nor suggested in either Foster or Jackowski, as well as in the lack of a reasonable expectation that the asserted combination of teachings from Foster and Jackowski would be successful, it is respectfully submitted that one of ordinary skill in the art would not have been motivated to have combined the teachings of Foster and Jackowski in the manner that has been asserted. Rather, based on the deficiencies of these references, it appears that any such motivation could only have been improperly gleaned from the disclosure of the above-referenced application.

In view of the foregoing, it is respectfully submitted that a *prima facie* case of obviousness has not been established against the subject matter recited in amended independent claim 21. Accordingly, it is respectfully submitted that, under 35 U.S.C. § 103(a), amended independent claim 21 recites subject matter which is allowable over that taught in Foster and Jackowski.

Claims 22-33 and 46 are each allowable, among other reasons, for depending either directly or indirectly from claim 21, which is allowable.

Claim 22 is additionally allowable because neither Foster nor Jackowski teaches or suggests an assay system that includes a waveguide which is optically associated with a rear lens oriented for reading light passing through the waveguide to monitor coupling efficiency and beam quality. Rather than teaching an assay system that includes lenses that are oriented for “reading light,” the disclosure at col. 7, line 66, to col. 8, line 2 of Foster is limited to use of lenses to shape light that exits a waveguide.

Claim 26 is further allowable since Foster and Jackowski both lack any teachings or suggestion of a controller that is configured to effect correlation of at least one indicator of coronary artery disease in a liquid biological sample in a continuous fashion. Instead, the disclosure at col. 8, lines 60-63, and col. 9, line 29, to col. 10, line 40 of Foster is limited to reading data obtained at a specific point in time. *See, e.g.,* col. 9, lines 64-65.

Claim 27 depends from claim 26 and is also allowable since Foster and Jackowski do not teach or suggest a controller which is configured to effect monitoring and correlating until a

reliable determination is made of whether at least one indicator is coronary artery disease is present in a liquid biological sample in an amount indicative of coronary artery disease. The disclosure at col. 9, line 29, to col. 10, line 40, of Foster is limited to a preferred embodiment of electronics that appears to be useful for effecting a single sweep of a surface of an SPR-type waveguide with a CCD and process the data obtained during that sweep.

Claim 29 is further allowable because Foster and Jackowski both lack any teaching or suggestion of a controller which is configured to effect monitoring and correlating until a reliable determination is made of whether at least one indicator is coronary artery disease is present in a liquid biological sample in an amount indicative of coronary artery disease. Again, the disclosure at col. 9, line 29, to col. 10, line 40, of Foster is limited to a preferred embodiment of electronics that appears to be useful for effecting a single sweep of a surface of an SPR-type waveguide with a CCD and process the data obtained during that sweep.

Claim 31 is additionally allowable since neither Foster nor Jackowski teaches or suggests an assay system that includes a waveguide and a controller that is configured to substantially simultaneously determine concentrations of a plurality of indicators of coronary artery disease. Instead, the disclosure of Foster at col. 8, lines 60-63, and col. 9, line 29, to col. 10, line 40, thereof is limited to a system in which a *single sample* and references may be simultaneously “run” and detected.

Foster in View of Jackowski and, Further, in View of Herron

Claim 45 has been rejected under 35 U.S.C. § 103(a) for being drawn to subject matter which is purportedly unpatentable over the teachings of Foster, in view of teachings from Jackowski and, further, in view of the subject matter taught in U.S. Patent 5,512,492 to Herron et al. (hereinafter “Herron”).

Claim 45 is allowable, among other reasons, for depending directly from claim 21, which is allowable.

For the foregoing reasons, it is respectfully requested that the 35 U.S.C. § 103(a) rejections of claims 21-33, 45, and 46 be withdrawn.



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CONCLUSION

It is respectfully submitted that each of claims 21-33, 45, and 46 is allowable. An early notice of the allowability of each of these claims is respectfully solicited, as is an indication that the above-referenced application has been passed for issuance. If any issues preventing allowance of the above-referenced application remain which might be resolved by way of a telephone conference, the Office is kindly invited to contact the undersigned attorney.

Respectfully submitted,

A handwritten signature in black ink that appears to read "Brick G. Power".

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